

219,031  
Application Serial No. 09/213,031

Docket No. 2629-4005US1

molecular analysis. This Declaration addresses the Examiner's earlier concerns including cell lysis conditions.

Dunphy teaches that PEG, having a molecular weight between 7000 and 8000, is preferred for stabilizing cellular samples. However, the experiments performed as described in the enclosed Declaration demonstrate that glutaraldehyde may be effectively used as a fixative in Digene's UCMi formulations.

The Examiner contends that the use of EDTA to help stabilize nucleic acids would have been obvious to one skilled in the art since EDTA is a chelating agent that may reduce DNase activity. The experiments described in the enclosed Declaration demonstrate that the addition of EDTA in Digene's UCMi formulations does help stabilize cellular DNA that is stored at room temperature over a period of four weeks. However, the addition of EDTA to Dunphy's formulations fails to stabilize the nucleic acids, as determined by little detectable signal from the HPV positive samples.

Since DNA is known to be unstable when stored for longer periods of time in an acidic environment (JJ Green, Rao VB. Recombinant DNA Principles and Methodologies. Marcel Dekker, USA 1998, p. 23), Dunphy's formulations were neutralized to determine if neutralizing the pH would stabilize the nucleic acids. However, nucleic acids stored in any of the Dunphy's media could not be detected.

Therefore, these experiments have demonstrated that Dunphy's media are not suitable for the storage of nucleic acids, in any variation. These experiments further confirm that the formulation of the instant invention, however, is suitable for molecular analysis of cellular nucleic acids. The formulation taught by Dunphy does not anticipate or make obvious the UCM media. In fact, the formulation taught by Dunphy cannot provide direct molecular analysis of cells according to the instant claims because the Dunphy composition quickly degrades the nucleic acids in the sample.

Favorable consideration of the present application and claims in view of the Declaration submitted herewith is respectfully request. Early and favorable action by the Examiner is earnestly solicited. No new matter is added by the instant amendment.

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AUTHORIZATION

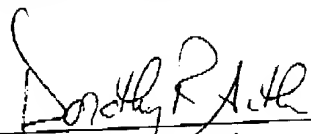
No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2629-4005US1.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition and for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2629-4005US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

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By:   
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